

To the kind attention of Prof. S. Hoshide  
Editor-in-chief  
Blood Pressure Monitoring

Padova, January 28, 2026

Dear Editor,

Attached please find our short paper “**Blood pressure measurement using a wide-range conical cuff from 22 to 45 cm of arm circumference: Validation of the Prolife PX7 Premium, an upper-arm blood pressure monitor with Inflation Mode Technology (IMT) evaluated in a general population according to the ISO 81060-2:2018 + Amd1:2020/Amd2:2024 protocol.**”, that we submit for publication in Blood Pressure Monitoring.

The manuscript has been read and approved by all authors, the requirements for authorship have been met, and each author believes the manuscript represents honest work

No author has conflict of interest with the present material.

The procedures followed were in accordance with institutional guidelines.

I hereby state that the manuscript has not been published nor has it been submitted to any other journal.

Suitable reviewer for this article may be a Scientist involved in validation studies:

Dr Gianfranco Parati, Italy: [gianfranco.parati@unimib.it](mailto:gianfranco.parati@unimib.it)

With best regards,

Claudio Fania, MD

**Blood pressure measurement using a wide-range conical cuff from 22 to 45 cm of arm circumference: Validation of the Prolife PX7 Premium, an upper-arm blood pressure monitor with Inflation Mode Technology (IMT) evaluated in a general population according to the ISO 81060-2:2018 + Amd1:2020/Amd2:2024 protocol.**

<sup>1</sup>Claudio Fania, <sup>1</sup>Elena Meggiolaro, <sup>1</sup>Debora De Franceschi, Paolo Palatini<sup>2</sup>

<sup>1</sup>ARCELLA Outpatient Clinic, Padua, Italy,

<sup>2</sup>Studium Patavinum, Department of Medicine, University of Padova, Padua, Italy

**Running head:** wide-range device validation

Conflicts of interest: none

Address correspondence to:

Doctor Claudio Fania, via Tiziano Aspetti 106, 35133-Padova, Italy

e-mail: [faniamail@gmail.com](mailto:faniamail@gmail.com)

## **SUMMARY**

**Objective.** To determine the accuracy of the Prolife PX7 Premium monitor for upper arm blood pressure (BP) measurement according to the International Organization for Standardization (ISO) 81060-2:2018 /Amd1:2020/Amd2:2024 protocol.

**Methods.** The Prolife PX7 Premium device, an oscillometric fully automatic BP monitor designed for BP measurement by both healthcare professionals and home users, is provided with a single wide-range conical cuff suitable for arm circumferences ranging from 22 to 45 cm. The device was tested in 86 subjects from the general population (52.3% men) with a mean age of 43.2 years.

**Results.** The mean device–observer systolic and diastolic BP differences and their standard deviations were in agreement with criterion 1 of the protocol requirements ( $\leq 5 \pm 8$  mmHg) being  $4.3 \pm 4.4$  mmHg and  $3.4 \pm 4.3$  mmHg, respectively. The measurement errors were unrelated to the arm sizes. Also criterion 2 of the ISO 81060-2:2018 /Amd1:2020/Amd2:2024 protocol was satisfied. The Standard deviations of systolic and diastolic BPs were 4.2 mmHg and 4.1 mmHg, respectively, well below the maximum values required by the protocol (5.49 and 5.56 mmHg for systolic and diastolic BPs, respectively).

**Conclusions.** The present results show that the Prolife PX7 Premium monitor satisfied the requirements of the ISO 81060-2:2018 /Amd1:2020/Amd2:2024 protocol for the general population, demonstrating that a single cuff designed for a wide range of arm sizes can provide reliable measurements across a 22-45 cm range of arm circumferences.

**Key-words:** blood pressure; wide-range; cuff; device; validation; measurement

## **Introduction**

In past years, most devices for blood pressure (BP) measurement have been validated using two versions of the International Protocol of the European Society of Hypertension (ESH) (1,2) or the British Hypertension Society protocol (3). However, an important drawback of these protocols was that arm size was not included among the selection criteria for subject enrolment. The advent of so called wide-range cuffs highlighted this limitation because of the importance of testing an adequate number of subjects with arm circumferences at the extremes of the declared range. A revision of the International Organization for Standardization (ISO) protocol (81060-2:2018), published in 2018 (4-7) and two more recent amendments (Amd1:2020/Amd2:2024), filled this gap establishing that a sphygmomanometer intended for use with a single cuff should be tested in an adequate number of subjects across the full range of arm circumferences.

The aim of this study was to test the accuracy of the Prolife PX7 Premium monitor, an oscillometric fully automatic BP monitor, according to the recommendations of the new Universal Standard (4-7) and its Amendments, using a single cuff covering a wide range of arm circumferences.

## **Subjects and methods**

### **Participants**

Study participants older than 12 years were recruited from among the outpatients of Poliambulatorio Arcella, Padua, Italy. Their mean (SD) upper arm circumference was  $32.1 \pm 7.1$  cm, and their BP at entry was  $133.3 \pm 25.9/81.5 \pm 18.6$  mmHg. The distribution of upper arm circumference was in accordance with ISO 81060-2:2018/Amd 1 requirements for a device provided with a single cuff (4-7). The study was performed in accordance with the harmonized standard EN ISO 14155:2020 (Clinical investigation of medical devices for human subjects - Good clinical practice) and was approved by the Institutional Review Board of the Poliambulatorio Arcella, Padua, Italy. Written informed consent was obtained from all participants.

## **Device and cuff**

The Prolife PX7 Premium monitor is an oscillometric upper-arm fully automatic device designed for BP measurement by both healthcare professionals and home users, developed by Montex Swiss AG, Tramstrasse 16, 9442 Berneck, Switzerland (figure 1). The Monitor automatically stores the 199 last measurement values. By pressing the MEMORY button, an average value of the last 3 measurements as well as the last measurement and the further last 198 measurements can be displayed. The measurement range is 60-255 mmHg for systolic BP and 30-199 mmHg for diastolic BP. Data can be transferred to a PC or smartphone via Bluetooth technology. The Prolife PX7 Premium Blood Pressure Monitor is equipped with Prolife AIM technology, which incorporates artificial intelligence–assisted algorithmic logic to optimize the BP measurement process and the detection of Atrial Fibrillation (AF) by AFibra® technology in every single BP measurement. The AF detection function was not part of this clinical study. The dimensions of the device are 175 x 92 x 54mm, and the weight is approximately 288g without batteries and cuff. The wide-range conical cuff used in the present study (figure 1) is suitable for arm circumferences ranging from 22 cm to 45 cm. It has a proximal circumference of 49 cm, and a distal circumference (above the elbow) of 43 cm. For a slant height of 13 cm, this leads to a calculated truncated cone slant angle of 85.8°. The cuff is designed as a soft D-ring cuff for best possible adjustment to various arm shapes (cylindrical shape, ball shape), which is particularly important in the very upper arm size segment. The inner bladder of the cuff has a rectangular shape.

## **Procedures**

The clinical study was performed by a supervisor, Claudio Fania, who took the three device measurements and by two trained observers (Elena Meggiolaro and Debora De Franceschi) who had received adequate training from an expert in BP measurement. BP measurements were taken by the observers with a standard mercury sphygmomanometer in the upper arm, using an adult cuff with a bladder that was at least 75% of the arm circumference and had a width that was at least 37% of the same (4-7). In our laboratory we use cuffs with a progressive increase in width of 2 cm, to

cover the entire range of adult arm sizes. For large and extra-large arms we use conical cuffs. The dimensions of the cuffs used in the present study are reported in table 1. The reference sphygmomanometer was calibrated according to the ISO81060-2:2018 protocol before the study. Upper arm circumference was measured at the midpoint between the acromion and olecranon. The two observers were blinded to the measurements obtained from each other and the device readings. The validation was conducted by performing sequential same-arm measurements following the ISO81060-2 2018 standard section 5.2.4.1, with the participants in the sitting position (4). Two BP measurements were performed at entry (reference R0 and test device T0). Thereafter, four sequential readings were taken by observers 1 and 2 (BP1, BP3, BP5, and BP7), and three BP readings were taken by the supervisor using the test instrument (BP2, BP4, and BP6) coupled to a cuff of appropriate size.

## **Analysis**

To establish device accuracy, the required criteria 1 and 2 of the ISO81060-2 2018 protocol were applied. The device-observer BP differences are expressed as mean  $\pm$ SD. According to criterion 1, the mean device-observer BP difference should be  $\leq 5$  mmHg and the standard deviation  $\leq \pm 8$  mmHg. According to criterion 2, the maximum permissible standard deviation is a function of the mean device-observer BP difference, as reported in table 1 of the ISO protocol. Analyses were performed using Systat version 12 (SPSS Inc., Chicago, IL, USA). MedCalc version 19 (MedCalc Software, Ostend, Belgium) was used to generate the Bland-Altman plots (8).

## **Results**

A total of 96 participants were recruited. Ten subjects were not included in the analysis. Of these, five were excluded because of BP classes already covered, three because of reference SBP differences differed by more than 12 mmHg and/or DBP differences differed by more than 8 mmHg, and two for between observer BP differences  $> 4$  mmHg. Thus, 86 participants with four observers and three valid device BP readings were considered for the analysis. The participants'

characteristics, arms, and BP distributions are displayed in tables 2 and 3. All participants' characteristics satisfied the requirements of the ISO protocol.

The mean device–observer difference in the 258 separate BP data pairs was  $4.3 \pm 4.4$  mmHg for systolic BP and was  $3.4 \pm 4.3$  mmHg for diastolic BP (table 4). These data were in agreement with criterion 1 of the standard protocol requirements ( $\leq 5 \pm 8$  mm Hg). Also criterion 2 was satisfied being the Standard Deviations below the maximum values required by the protocol (5.49 and 5.56 mmHg, respectively, for systolic and diastolic BP) (table 3).

Plots of the device-observer BP differences according to systolic BP and diastolic BP distributions are shown in figures 2. Plots of device-observer BP differences according to arm circumference are shown in figure 3.

## **Discussion**

The present results show that the Prolife PX7 Premium upper-arm BP monitor provided with a single wide-range cuff fulfilled the requirements of the ISO 81060-2:2018 /Amd1:2020 /Amd2:2024 protocol for use in a general adult population. The device satisfied both protocol criteria 1 and 2 with a comfortably low standard deviation of 4.4mmHg and 4.3mmHg for SBP and DBP, respectively, after criterion 1. It is noteworthy to observe that the good performance obtained also in the largest arms (see figure 3) was likely to be due to the conical shape of the cuff which can provide more reliable measurements in large and extra-large arms (9-12).

The Prolife PX7 Premium is so far the first inflationary BP monitor which satisfies the stringent ISO81060-2 Amd1 criteria for a wide arm circumference range of 22 ~ 45cm. Advantages of the inflationary measurement method are an approx. 1.5 times shorter measurement time than deflationary measurements, with an at the same time lower pressure burden for the patient because no over pressure beyond SBP is needed. The hereby improved measurement comfort contributes to less measurement induced BP variation. Regarding the device mean deviation of 4.3 and 3.4mmHg for SBP and DBP respectively, before any downward adjustment within the ISO standard criteria

maybe thought, more data should be seen first also from other centers and patient groups, for a solid statistical justification.

## **Conclusions**

The present results show that the Prolife PX7 Premium upper-arm BP monitor satisfies the ISO 81060-2:2018/Amd1:2020/Amd2:2024 protocol requirements for the general population across a wide range of arm sizes.

## **Acknowledgements**

This study was funded by a grant from Montex Swiss AG (Switzerland).

## **References**

1. O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, et al., on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. International protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002; 7:3-17.
2. O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, et al; on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. European Society of Hypertension International Protocol revision 2010 for the Validation of Blood Pressure Measuring Devices In Adults. *Blood Press Monit* 2010;15:23-38.
3. O'Brien E, Petrie J, Littler WA, de Swiet M, Padfield PL, Altman D, et al. The British Hypertension Society Protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; 11(suppl 2):S43-S63.
4. Stergiou GS, Palatini P, Asmar R, Ioannidis JP, Kollias A, Lacy P, et al. A Universal Standard for the Validation of Blood Pressure Measuring Devices: Association for the

- Advancement of Medical Instrumentation/ European Society of Hypertension/ International Organization for Standardization (AAMI/ESH/ISO) Collaboration Statement. *J Hypertens* 2019; 37:459-466.
5. International Organization for Standardization. ISO 81060-2:2018. Noninvasive sphygmomanometers: part 2: clinical investigation of intermittent automated measurement type. 2018. <https://www.iso.org/standard/73339.html>.
  6. International Organization for Standardization. ISO 81060-2:2018/Amd 1:2020. Non-invasive sphygmomanometers – part 2: clinical investigation of intermittent automated measurement type – Amendment 1, 2020. <https://www.iso.org/standard/75432.html>.
  7. International Organization for Standardization. ISO 81060-2:2018/AMD 2:2024 non-invasive sphygmomanometers– part 2: clinical investigation of intermittent automated measurement type–amendment 2, 2024. <https://www.iso.org/standard/83598.html> .
  8. <https://www.medcalc.org/manual> for more help with MedCalc. [Accessed 16 November 2019].
  9. Palatini P, Frick GN. Cuff and bladder: overlooked components of BP measurement devices in the modern era? *Am J Hypertens* 2012;25:136-138.
  10. Palatini P, Parati G. Blood pressure measurement in very obese patients: a challenging problem. *J Hypertens* 2011; 29: 425-429.
  11. Palatini P, Benetti E, Fania C, Saladini. Only troncoconical cuffs can provide accurate blood pressure measurements in people with severe obesity. *J Hypertens* 2019; 37: 37-41.
  12. Bonso E, Saladini F, Zanier A, Benetti E, Dorigatti F, Palatini P. Accuracy of a single rigid conical cuff with standard-size bladder coupled to an automatic oscillometric device over a wide range of arm circumferences. *Hypertens Res* 2010;33:1186-1191.



### **Legend to figures**

**Figure 1.** Image of the device with its conical cuff.

**Figure 2.** Scatter plots of systolic and diastolic blood pressure differences between the device and the observers (y-axis) against the average of the test device and observer pressure values (x-axis) in 86 participants.

**Figure 3.** Scatter plots of systolic and diastolic blood pressure differences between the device and the observers (y-axis) against the circumference of the upper arm measured at midpoint (x-axis) in the 86 participants.

**Table 1.** Dimensions of the four cuffs used in the participants.

	<b>Group 1</b>	<b>Group 2</b>	<b>Group 3</b>	<b>Group 4*</b>
<b>Arm size (cm)</b>	<b>22-27</b>	<b>27.5-32</b>	<b>32.5-37</b>	<b>37.5-44.0</b>
Proximal length, cm	22	26	30	38.2
Middle length, cm	22	26	30	34
Distal length, cm	22	26	30	29.8
Width, cm	11	13	15	17
Slant angle, °	90	90	90	85.5

\*In the participants with 37.5-44.0 cm arm circumference a tronco-conical cuff was used.

**Table 2.** Characteristics of the participants enrolled in the study. Protocol requirements and study results.

	<b>Standard</b>	<b>Result</b>		<b>Judgment</b>
Number of subjects	85 people or more	86 people		PASS
Number of Measurement	7 times or more	7 times		PASS
Observer	2 people	2 people		PASS
Observer difference	±4mmHg or less	±4mmHg or less		PASS
Gender	Male 30% or more	45 people	52.3%	PASS
	Female 30% or more	41 people	47.7%	
Age	>12 years old: 100%	86 people (mean age, 43.2 ys)	100%	PASS

**Table 3.** Participants' arm size distribution and blood pressure range.

Arm circumference	Upper 50% = 41% Lower 50% = 59%	PASS
	Upper 25% = 20% 3rd 25% = 21% 2nd 25% = 28% Lower 25% = 31% Upper 12.5% = 15% Lower 12.5% = 15%	
Range of blood pressure	SBP $\geq$ 160 15% SBP $\geq$ 140 36% SBP $\leq$ 100 22% DBP $\geq$ 100 17% DBP $\geq$ 85 33% DBP $\leq$ 60 19%	PASS

SBP indicates systolic blood pressure; DBP, diastolic blood pressure.

**Table 4.** Results of the validation for the Prolife PX7 Premium upper-arm BP monitor according to the ISO protocol.

Measurement result	(Criterion1)		(Criterion1)		
	Mean value	±5mmHg or less	SBP	4.3	PASS
			DBP	3.4	PASS
	Standard deviation	8mmHg or less	SBP	4.4	PASS
			DBP	4.3	PASS
	(Criterion2)		(Criterion2)		
	Standard Deviation (Refer to Table 1)	5.49 mmHg or less	SBP	4.2	PASS
		5.56 mmHg or less	DBP	4.1	PASS